

(19) World Intellectual Property Organization  
International Bureau



(43) International Publication Date  
9 August 2001 (09.08.2001)

PCT

(10) International Publication Number  
**WO 01/57238 A3**

(51) International Patent Classification<sup>7</sup>: **G01N 27/327**,  
C12Q 1/00

(21) International Application Number: PCT/US01/02510

(22) International Filing Date: 25 January 2001 (25.01.2001)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:  
09/497,269 2 February 2000 (02.02.2000) US

(71) Applicant: **LIFESCAN, INC.** [US/US]; 1000 Gibraltar Drive, Milpitas, CA 95035-6312 (US).

(72) Inventors: **YU, Yeung, Siu**; 3158 Paseo Robles, Pleasanton, CA 94560 (US). **SHAH, Mahesh**; 1759 Jones, Santa Clara, CA 95051 (US).

(74) Agent: **FIELD, Bret, E.**; Bozicevic, Field & Francis LLP, Suite 200, 200 Middlefield Road, Menlo Park, CA 94025 (US).

(81) Designated States (*national*): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CR, CU, CZ, DE, DK, DM, DZ, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, UZ, VN, YU, ZA, ZW.

(84) Designated States (*regional*): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

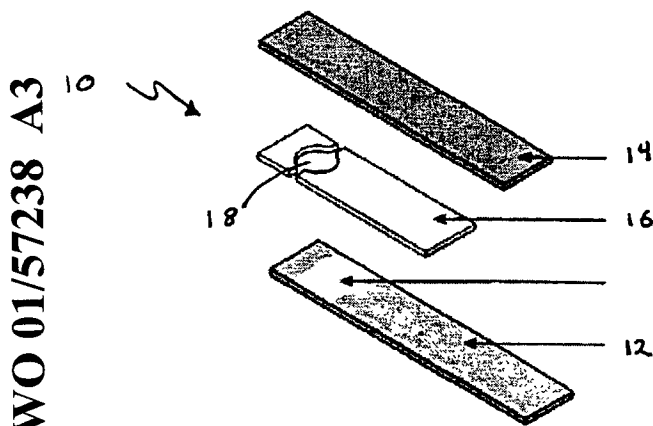
**Published:**

— with international search report

(88) Date of publication of the international search report:  
18 April 2002

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: ELECTROCHEMICAL TEST STRIP FOR USE IN ANALYTE DETERMINATION



(57) Abstract: Electrochemical test strips and methods for their use in the detection of an analyte in a physiological sample are provided. The subject test strips have a reaction zone defined by opposing metal electrodes separated by a thin spacer layer. The metal surface of at least one of the electrodes is modified by a homogenous surface modification layer made up of linear self-assembling molecules having a first sulfhydryl end group and a second sulfonate end group separated by a short chain alkyl linking group, where 2-mercaptoethane sulfonic acid or a salt thereof is preferred in certain embodiments. The subject electrochemical test strips find application in the detection of a wide variety of analytes, and are particularly suited for use the detection of glucose.

# INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 01/02510

**A. CLASSIFICATION OF SUBJECT MATTER**  
IPC 7 G01N27/327 C12Q1/00

According to International Patent Classification (IPC) or to both national classification and IPC

**B. FIELDS SEARCHED**

Minimum documentation searched (classification system followed by classification symbols)  
IPC 7 C12Q G01N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, CHEM ABS Data, BIOSIS, MEDLINE, WPI Data, PAJ

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 030 310 A (WOGOMAN FRANK W) 9 July 1991 (1991-07-09) abstract	1,6,12, 16,21
A	EP 0 971 036 A (KYOTO DAIICHI KAGAKU KK) 12 January 2000 (2000-01-12) examples	1,6,12, 16,21
A	WO 99 19507 A (FORROW NIGEL J ;WALTERS STEPHEN (GB); WATKIN JARED L (GB); ABBOTT) 22 April 1999 (1999-04-22) examples	1,6,12, 16,21
	--- -/--	

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

\* Special categories of cited documents :

- \*A\* document defining the general state of the art which is not considered to be of particular relevance
- \*E\* earlier document but published on or after the international filing date
- \*L\* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- \*O\* document referring to an oral disclosure, use, exhibition or other means
- \*P\* document published prior to the international filing date but later than the priority date claimed

- \*T\* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- \*X\* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- \*Y\* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- \*&\* document member of the same patent family

Date of the actual completion of the international search

18 January 2002

Date of mailing of the international search report

28/01/2002

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2  
NL - 2280 HV Rijswijk  
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,  
Fax: (+31-70) 340-3016

Authorized officer

Moreno, C

# INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 01/02510

## C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	<p>NUNES, G. S. ET AL: "Evaluation of a highly sensitive amperometric biosensor with low cholinesterase charge immobilized on a chemically modified carbon paste electrode for trace determination of carbamates in fruit, vegetable and water samples"</p> <p>ANAL. CHIM. ACTA (1999), 399(1-2), 37-49 , XP001058432</p> <p>the whole document</p> <p>---</p>	<p>1,6,12, 16,21</p>
A	<p>SHIMOJO, NOBUO ET AL: "Electrochemical assay system with single-use electrode strip for measuring lactate in whole blood"</p> <p>CLIN. CHEM. (WASHINGTON, D. C.) (1993), 39(11, PT. 1), 2312-14 , XP001052849</p> <p>the whole document</p> <p>-----</p>	<p>1,6,12, 16,21</p>

# INTERNATIONAL SEARCH REPORT

Information on patent family members

Interr. Application No

PCT/US 01/02510

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
US 5030310	A	09-07-1991	US 4938860 A	03-07-1990
			AU 569660 B2	11-02-1988
			AU 5842686 A	29-01-1987
			CA 1250019 A1	14-02-1989
			DE 3677827 D1	11-04-1991
			EP 0206218 A2	30-12-1986
			JP 1899735 C	27-01-1995
			JP 6029874 B	20-04-1994
			JP 62005171 A	12-01-1987
EP 0971036	A	12-01-2000	JP 8278276 A	22-10-1996
			EP 0971036 A1	12-01-2000
			CN 1139757 A	08-01-1997
			DE 69614172 D1	06-09-2001
			EP 0736607 A1	09-10-1996
			US 5720862 A	24-02-1998
WO 9919507	A	22-04-1999	AU 1090999 A	03-05-1999
			BR 9814086 A	03-10-2000
			EP 1023455 A1	02-08-2000
			JP 2001520367 T	30-10-2001
			WO 9919507 A1	22-04-1999